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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/810,780 | 03/25/2004 | Benjamin Sullivan | 38055.00004.CIP1 | 9606 |
| 23562 | 7590 | 12/09/2005 | EXAMINER | |
| BAKER & MCKENZIE PATENT DEPARTMENT 2001 ROSS AVENUE SUITE 2300 DALLAS, TX 75201 | | | CHRISTENSEN, RYAN S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 2856 | |

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,780

Applicant(s)

SULLIVAN ET AL.

Examiner

Ryan Christensen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/25/204.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-28 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,16,29-31,33-38 is/are rejected.
- 7) ☒ Claim(s) 3,10-15,32 and 39-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 8, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,005,403 (Steudle). With respect to claim 1, Steundle discloses a method of determining the osmolarity of a fluid sample (abstract), comprising: generating sample data for the fluid sample (Fig. 7A); accounting for transient effects in the sample data (Fig. 7A, and Col. 11, lines 40-51); determining a value associated with a initial point of placement for the sample fluid once the transient effects are accounted for (Fig. 7, and Col. 11, lines 52-56); and using the determined value to obtain an osmolarity measurement for the fluid sample (Fig. 7B and 7C).

With respect to claim 2, Steundle discloses determining the initial point of placement after the sample data is generated (Fig. 7, and Col. 11, lines 52-56).

With respect to claim 4, Steudle discloses using the determined value to obtain an osmolarity measurement comprises subtracting a baseline value from the determined value and using the resulting difference value to determine the osmolarity measurement (Col. 11, lines 57-70).

With respect to claim 5, Steudle discloses obtaining the osmolarity measurement comprises using the resulting difference to look up an osmolarity value based on a calibration curve (Fig. 7B and 7C).

With respect to claim 8, Steudle discloses determining a value associated with the initial point of placement comprises fitting a curve to a portion of the sample data once the transient effect is accounted for and extrapolating the value using the curve (Fig. 7, and Col. 14, lines 4-21).

With respect to claim 9, Steudle discloses fitting the curve to a portion of the sample data comprises performing a linear regression (Fig. 7B and 7C).

With respect to claim 16, Steudle discloses determining the initial point of placement comprises taking the derivative of the signal waveform and finding the sample at which the derivative is at its maximum (Col. 12 lines 22-49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,005,403 (Steundle) in view of U.S. Patent 5,461,699 (Arbabi). Steundle discloses the claimed invention except for determining the osmolarity measurement is performed using a neural network. Arbabi discloses a neural network as a system for

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statistical forecasting (abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention modify the system disclosed in Steundle by analyzing the data with a neural network because it is well known in the art to use neural networks for regressions and other advanced statistical calculations or forecasts.

Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,005,403 (Steundle) in view of U.S. Patent 4,951,683 (Davis). With respect to claim 7, Steundle discloses the claimed invention except for determining the osmolarity measurement is performed using embedded circuitry. Davis discloses a device for determining osmolarity based on the conductive properties of tear film including a microprocessor (Col. 6 lines 15-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system taught in Steundle with embedded circuitry for determining osmolarity because microprocessor are more efficient than hand calculations. Further, automation is considered within the ordinary skill of the art.

Claims 29-31 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,951,683 (Davis) in view of U.S. Patent 5,005,403 (Steundle). With respect to claim 29, Davis discloses an osmolarity measurement system (abstract), comprising measurement device (Col. 2, lines 41-44) configured to receive a fluid sample and generate sample data for the fluid sample (Col. 3 lines 43-47); and a processing device coupled with the measurement device (Col. 6, lines 15-31). Davis does not explicitly disclose, the processing device configured to account for transient effects in the sample data, determining a value associated with a initial point of

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placement for the fluid sample once the transient effects are accounted for, and using the determined value to obtain an osmolarity measurement for the fluid sample.

Stuedle discloses accounting for transient effects in the sample data (Fig. 7A, and Col. 11, lines 40-51); determining a value associated with a initial point of placement for the fluid sample once the transient effects are accounted for (Fig. 7, and Col. 11, lines 52-56); and using the determined value to obtain an osmolarity measurement for the fluid sample (Fig. 7B and 7C). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the system taught in Davis by configuring the microprocessor with the improvements taught in Stuedle in order to convert the data into an osmolarity reading as suggested in Davis (Col. 6 lines 15-31).

With respect to claim 30, the combination of Davis and Steundle further discloses the measurement device is configured to receive a sample receiving chip (Davis, Fig. 2), the sample receiving chip comprising a substrate (Davis, Fig. 2, 16) that receives an aliquot volume of a fluid sample and a sample region of the substrate (Davis, Fig. 5), sized such that the volume of the fluid sample is sufficient to operatively cover a portion of the sample region (Davis, Fig. 1 and 5 and Col. 4 line 67 to Col. 5, line 1), whereupon energy properties of the fluid sample can be detected from the sample region to produce the sample data (Davis, Col. 6 lines 15-31).

With respect to claim 31, the combination of Davis and Steundle further discloses, the processing device is further configured to determine the initial point of placement based on the sample data after the sample data is generated (Stuedle, Fig. 7, and Col. 11, lines 52-56).

With respect to claim 33, the combination of Davis and Steundle further discloses, the processing device is further configured to account for the effects of evaporation before determining the value associated with the initial point of placement (Steundle, Col. 11, lines 57-70).

With respect to claim 34, the combination of Davis and Steundle further discloses, obtaining the osmolarity measurement comprises using the resulting difference to look up an osmolarity value based on a calibration curve (Steundle, Col. 11, lines 57-70).

With respect to claim 35, the combination of Davis and Steundle further discloses, a memory coupled with the processing device, the memory configured to store the calibration curve values (Davis, Col. 6 lines 15-31).

With respect to claim 37, the combination of Davis and Steundle further discloses, the processing device is configured to determine a value associated with the initial point of placement by fitting a curve to a portion of the sample data once the transient effect is accounted for and extrapolating the value using the curve (Steundle, Fig. 7, and Col. 14, lines 4-21).

With respect to claim 38, the combination of Davis and Steundle further discloses fitting the curve to a portion of the sample data comprises performing a linear regression (Steundle, Fig. 7B and 7C).

With respect to claim 43, the combination of Davis and Steundle further discloses
With respect to claim 16, Steundle discloses determining the initial point of placement

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comprises taking the derivative of the signal waveform and finding the sample at which the derivative is at its maximum (Steundle, Col. 12 lines 22-49)

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U.S. Patent 5,005,403 (Steundle) and U.S. Patent 4,951,683 (Davis) in view of U.S. Patent 5,461,699 (Arbabi). The combination of Davis and Steundle discloses all the limitation of the claimed invention except they do not disclose wherein the processing device comprises a neural network. Arbabi discloses a neural network as a system for statistical forecasting (abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention modify the system disclosed in Steundle by analyzing the data with a neural network because it is well known in the art to use neural networks for regressions and other advanced statistical calculations or forecasts.

Allowable Subject Matter

Claims 17-28 are allowed. The following is an examiner's statement of reasons for allowance:

With respect to claim 17, the primary reason for the allowance is the inclusion of accounting for the effects of evaporation before determining the value associated with the initial point of placement. It is these features found in the claim, as they are claimed in the combination that has not been found, taught or suggested by the prior art of record, which makes this claim allowable over the prior art. U.S. Patent 5,005,403 (Steundle) discloses a system and method for determining osmolarity. The disclosure includes an initial point of placement, which is identified in several locations. Steundle

does not disclose or suggest accounting for evaporation. U.S. Patent 4,951,683 (Davis) discloses an apparatus for determining osmolarity of tear film. Davis does not disclose or suggest accounting for evaporation in the tear film sample. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 3, 10-15, 32, and 39-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Pertinent Prior Art

U.S. Patent 5,143,080 (York) discloses an apparatus for determining osmolarity of tear film.

U.S. Patent 4,996,993 (York) discloses an apparatus for determining osmolarity of tear film.

U.S. Patent 4,269,197 (Gilbard) discloses a pipette for taking samples of tear film.

U.S. Patent 5,665,904 (Boling) discloses an apparatus and method for determining the analyte content in a solution.

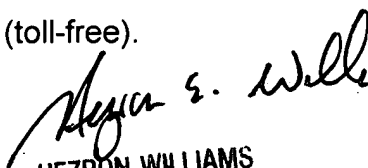
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Christensen whose telephone number is 571-272-2683. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSC


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